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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,360	03/20/2001	Michael S. German	UCSF-129CIP	2345

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EXAMINER	
WHITEMAN, BRIAN A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/817,360	GERMAN, MICHAEL S.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 6/15/04.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 12-14,16,18-23,25,27-30,37-45 is/are pending in the application.

4a) Of the above claim(s) 14,16,22,23 and 42 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 12, 13, 18-21, 25, 30, 37-41, 43-45 is/are rejected.

7)☒ Claim(s) 27-29 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6/15/04.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/15/04 has been entered.

Claims 12-14, 16, 18-23, 25, 27-30, and 37-45 are pending.

Applicant's traversal, the amendment to claims 12, 19, 25, 27-29, and 37-40, the addition of claims 41-45 in paper filed on 6/15/04 is acknowledged and considered.

The indicated allowability of claim 30 is withdrawn in view of the newly discovered 112 second paragraph rejection due to an amendment to the independent claim from which claim 30 depends from. A 112 second paragraph rejection follows.

Election/Restrictions

Claims 14, 16, 22, and 23 and new claim 42 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/29/02.

Claim Objections

Claims 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 30 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 recites the limitation "the precursor cell" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 45 recites the limitation "The method of claim 1" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 12, 13, 18, 19, 20, 21, 25, 30, 37, 38, 39, 40, 41, 43, and 44 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The instant claims read on a method of producing an insulin-producing cell in vitro comprising introducing a nucleic acid molecule encoding Ngn3 into a gastrointestinal cell in vitro.

US Patent 6,703,220 claims a method of producing a polypeptide comprising culturing a recombinant host cell containing a polynucleotide sequence encoding Ngn3 (SEQ ID NO: 2), under conditions for the expression of an encoded polypeptide. The claim does not specifically recite using a promoter to express the polynucleotide sequence, however, in order for the sequence to be expressed in a host cell a promoter would be required. The claim does not specifically recite what type of host cell or using Ngn3 to produce insulin-producing cells. However, in light of the specification, which teaches using Ngn3 to produce insulin-producing β cells (abstract and column 24) and in light of the definition of cells in the specification, the claim encompasses mammalian gastrointestinal organ cell, pancreatic cells, and liver cells and using Ngn3 to produce insulin-producing cells (columns 24 and 25).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12, 13, 18, 19, 20, 21, 25, 30, 37, 38, 39, 40, 41, 43, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6,703,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between the instant claims and the claim from '220 is that the instant claims recite a method of producing an insulin-producing cell *in vitro*, wherein the cell is a cultured gastrointestinal organ cell and the claim from '220 recites a method of producing a polypeptide comprising culturing a host cell containing an isolated polynucleotide encoding SEQ ID NO: 2 (Ngn3) under suitable conditions for the expression of an encoded polypeptide.

However, in light of the specification of '220, which teaches using Ngn3 to produce insulin-producing β cells (abstract and column 24) and the definition in the '220 specification for host cells (mammalian gastrointestinal organ cell, pancreatic cells, and liver cells, columns 24 and 25), the claim from '220 is an obvious variant of the instant claims. The claim from '220 is an obvious variant because using a mammalian gastrointestinal organ cell, pancreatic cells, and liver cells in the method would result in insulin-producing cells. In addition, the claim from '220 does not specifically recite using a promoter to express the polynucleotide sequence. However, in order for the polynucleotide sequence encoding Ngn3 to be expressed in a host cell in the claim from '220, a promoter would be required.

Claims 12, 13, 18, 19, 20, 21, 25, 30, 37, 38, 39, 40, 41, 43, and 44 are directed to an invention not patentably distinct from claim 5 of commonly assigned US Patent 6,703,220. Specifically, US Patent 6,703,220 claims a method of producing a polypeptide comprising culturing a recombinant host cell containing a polynucleotide sequence encoding Ngn3 (SEQ ID NO: 2), under conditions for the expression of an encoded polypeptide. The claim does not specifically recite using a promoter to express the polynucleotide sequence, however, in order for the polynucleotide sequence to be expressed in a host cell a promoter would be required. In addition, the claim does not specifically recite what type of host cell or using Ngn3 to produce insulin-producing cells. However, in light of the specification, which teaches using Ngn3 to produce insulin-producing β cells (abstract and column 24) and in light of the definition of cells in the specification, the claim encompasses mammalian gastrointestinal organ cell, pancreatic cells, and liver cells and using Ngn3 to produce insulin-producing cells (columns 24 and 25).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned patent, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Brian Whiteman
Patent Examiner, Group 1635

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER